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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,773	11/04/2003	Hongming Chen	TPI5020USNP	5482

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EXAMINER	
HYUN, PAUL SANG HWA	

ART UNIT	PAPER NUMBER
1797	

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12/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,773	CHEN ET AL.	
	Examiner	Art Unit	
	PAUL S. HYUN	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-22* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 7-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 27, 2008 has been entered.

Claims 1-5 and 7-22 remain pending. Claims 1-5 and 7-18 remain withdrawn. Applicant amended claim 19. In summary, claims 19-22 remain pending for examination on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims **19-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over McMahon et al. (US 6,004,967) in view of Mulye et al. (US 6,416,786 B1) and Lee et al. (US 2003/0230488 A1) as evidenced by www.wikipedia.com.

McMahon et al. disclose a method for determining the solubility of the pharmaceutical compound "A1" (see Table 1 in col. 19 for identity of A1) in various excipients wherein the pharmaceutical preparation can comprise solids or non-aqueous liquid (see lines 6-48, col. 17 and Table 4 in col. 20). Specifically, Table 4 shows the solubility of compound A1 having concentration of 10 mg/mL in two different concentrations of polysorbate-80 excipient. Polysorbate-80 has viscosity ~300-500 cP (see wikipedia.com wherein unit conversion for viscosity from cSt to cP is accomplished by multiplying viscosity of polysorbate-80 in cSt by its density in g/mL). The method disclosed by McMahon et al. differs from the claimed invention in that McMahon et al. do not disclose the steps of conducting the experiment in an array format. McMahon et al. also do not disclose the step of dispensing less than 250 microliters of the excipient using a positive displacement pump. Lastly, McMahon et al. do not disclose mixing excipients to explore the synergistic effects of mixing excipients.

With respect to the pump and the array, Lee et al. disclose an apparatus for conducting solubility tests (see [0005]). The apparatus comprises a microplate 12 (see [0047]), and a positive displacement pump (see [0039]) capable of dispensing 2-10 microliters of highly viscous liquid into the wells of the microplate (see [0067]-[0068]). In light of the disclosure of Lee et al., it would have been obvious to one of ordinary skill in the art to conduct the solubility test disclosed by McMahon et al. using the apparatus disclosed by Lee et al. The apparatus disclosed by Lee et al. would optimize the organization as well as the efficiency of the solubility test.

With respect to mixing excipients, Mulye et al. disclose that it is well known in the art to mix excipients because certain excipient mixtures exhibit unexpected synergistic effects (see lines 15-21, col. 2). In light of the disclosure of Mulye et al. it would have been obvious to mix excipients in the solubility test disclosed by McMahon et al. to explore the synergistic effects of certain excipient combinations.

Although neither McMahon et al. nor Lee et al. explicitly disclose the step of ranking the compounds based on solubility, it would have been obvious to one of ordinary skill in the art to do so once all the samples have been tested. Organizing test data according to increasing or decreasing value is within the skill of one of ordinary skill in the art.

With regards to claim 20, neither McMahon et al. nor Lee et al. explicitly disclose that degraded or decomposed samples are thrown out from the experiment. Nonetheless, it would have been obvious to one of ordinary skill in the art to selectively exclude decomposed or degraded samples to prevent skewed data caused by defective samples.

With respect to claim 21, it would have been obvious to one of ordinary skill in the art to expand the range of parameters (e.g. concentration of excipient, type of excipient) in the method disclosed by McMahon et al. such that more than 94 samples are prepared so that a more thorough data can be obtained.

Response to Arguments

Applicant's arguments with respect to claims 19-22 have been considered but they are moot in view of the new ground of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL S. HYUN whose telephone number is (571)272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul S Hyun/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797